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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,167	12/11/2001	Jonathan A. Usuka	9080-016-999	3878
20583	7590	03/19/2004	EXAMINER	
JONES DAY 222 EAST 41ST STREET NEW YORK, NY 10017			LY, CHEYNE D	
			ART UNIT	PAPER NUMBER

1631

DATE MAILED: 03/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,167	USUKA ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-26,28-50,52-61 and 71-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-13,16,18,19,23-26,28-38,41,43,44,48-50,52-57,59-61 and 71-77 is/are rejected.
- 7) ☒ Claim(s) 14,15,17,20-22,39,40,42,45-47 and 58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>11/25/03</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/03 & 12/01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments filed December 24, 2003 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The cancellation of claims 2, 27, 51, and 62-70 and the addition of claims 72-77 have been acknowledged.
3. The Terminal Disclaimer has been accepted.
4. Claims 1, 3-26, 28-50, 52-61, and 71-77 are examined on the merits.

OBJECTIONS

5. Claims 14, 15, 17, 20-22, 39, 40, 42, 45-47, and 58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CLAIM REJECTIONS - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 3-10, 12, 13, and 18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Luo et al. (1992).

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8. This rejection is maintained with respect to claims 1, 3-10, 12, 13, and 18, as recited in the previous office action mailed October 21, 2003.

9. This rejection is necessitated by Applicants amendments.

RESPONSE TO ARGUMENTS

10. Applicant argues by claims amendment and pointed to support that Luo et al. does not disclose the limitation of phenotypic data structure that comprises a difference in a phenotype between different strains of a species as exemplified on page 14, and 16, line 5, through page 18, line 12, of the instant specification. Applicant's argument and pointed to support has been fully considered and found to be unpersuasive as discussed below.

11. Specific to the pointed to support of page 14, and 16, line 5, through page 18, line 12, the instant specification states that the example pointed to by Applicant is one embodiment of the instant invention (page 14). Further, Applicant is reminded that the instant claims have been interpreted as broadly as reasonable. It is acknowledged that the pointed support recites one embodiment of constructing phenotypic data. However, without reading limitations from the specification into the instant claims, the cited phenotype structure of Luo et al. is consistent with the scope of the instant claimed invention.

12. Specific to the new limitations added by claims amendment, Luo et al. discloses a method for mapping of quantitative trait loci from two lines of tomatoes (different strains of a species) having different phenotypes such as fruit mass, soluble solids, and fruit pH (phenotype structure) (page 239, column 2, lines 14-33). Further, the amount of said genome

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that is included in each locus is predetermined as determined by chromosomes 1, 4, 6, 7, and 9 (page 240, column 1, lines 4-13).

35 U.S.C. 102(b) REJECTION IS RE-ITERATED

13. It is re-iterated that Luo et al. discloses a method implemented in a computer system comprising Fortran-77 and PASCAL computer programs for interval mapping of quantitative trait loci in an F2 population wherein the parameters comprises P1 and P2 strains (phenotype structure); three genotypes for each quantitative locus (QTL) and each marker gene identified in the genome. Marker linkage map is set up wherein the genome is separated into a series of chromosomal segments and each of which is flanked by two marker loci (genotype structure) (page 237, column 1, lines 1-17). The LOD score is established by scanning all possible sites throughout the interval and the LOD score has its maximum value will be the most likely location of the QTL (high correlation value relative to all other genotypic data structures) (page 237, column 1, line 37 to column 2, lines 1-4) and the steps are repeated iteratively (page 238, column 2, lines 4-6), as in instant claims 1, 9, 10, 12, 13, and 18.

14. The position of the QTL is centered between two marks (page 237, column 1, diagram), as in instant 5.

15. LOD is plotted wherein the plots are scaled by the length of the marked chromosome in centimorgans (cM) (page 239, column 2, lines 42-48 and Figure 1), as in instant claims 3, 4, and 6-8.

CLAIM REJECTIONS - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 1, 3-13, 16, 18, 19, 23-26, 28-38, 41, 43, 44, 48-50, 52-57, 59-61, and 71-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luo et al. (1992) taken with Blum (US 6,132,724 A).

19. This rejection is maintained with respect to claims 1, 3-13, 16, 18, 19, 23-26, 28-38, 41, 43, 44, 48-50, 52-57, 59-61, and 71, as recited in the previous office action mailed October 21, 2003. The instant rejection has been extended to new claims 72-77.

20. This rejection is necessitated by Applicants amendments.

RESPONSE TO ARGUMENTS

21. Specific to claims 1, 26, 52, and 71, Applicant argues in the response to the 35 U.S.C. § 102 rejection that Luo et al. does not disclose the phenotypic data structure as discussed above. Further, Luo et al. and Blum alone or in combination does not disclose said

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phenotypic data structure. The above response to the 35 U.S.C. 102(b) rejection has been extended to the instant 35 U.S.C. 103(a) rejection.

22. Specific to claims 11, 16, 19, and 44, Applicant argues that Luo et al. and Blum in combination does not disclose the limitations of the structures represent a difference between a first and second cluster of strains of a species as in claims 11 and 16; and single nucleotide polymorphism as in claims 19 and 44. Applicant's argument has been fully considered and found to be unpersuasive as discussed below.

23. Luo et al. discloses a method for mapping of quantitative trait loci from two lines of tomatoes (different strains of a species) having different phenotypes such as fruit mass, soluble solids, and fruit pH (phenotype structure) (page 239, column 2, lines 14-33). Blum discloses in sib pair linkage analysis the DRD2 A2 allele (genotype) has been found to associate with a number of behaviors (phenotype); a single point mutation in exon 8 of the DRD2 gene has been demonstrated; and the cluster of MCMI-II assessed schizoid/avoidant cluster compared to other Axis II diagnostic clusters (antisocial, narcissistic, paranoid) as directed to patients (column 7, lines 35-61). The combination of Luo et al. and Blum discloses the limitations of the structures represent a difference between a first and second cluster of strains of a species as in claims 11 and 16; and single nucleotide polymorphism as in claims 19 and 44. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a method of associating a phenotype with a candidate chromosome region(s) as directed to a phenotype wherein the said method comprises a clustering step and a genotype database as taught by Luo et al. and Blum.

35 U.S.C. 103(a) REJECTION IS RE-ITERATED

24. Luo et al. discloses the limitations of claims 1, 3-10, 12, 13, and 18 as discussed above.

Further, Luo et al. in combination with Blum disclose the limitations of claims new claims 72-77.

25. However, Luo et al. does not disclose wherein each element the phenotypic data structure represents a difference in said phenotype between a first cluster of strains of different organisms.

26. Blum discloses in sib pair linkage analysis the DRD2 A2 allele (genotype) has been found to associate with a number of behaviors (phenotype); a single point mutation in exon 8 of the DRD2 gene has been demonstrated; and the cluster of MCMI-II assessed schizoid/avoidant cluster compared to other Axis II diagnostic clusters (antisocial, narcissistic, paranoid) as directed to patients (column 7, lines 35-61), as in instant claims 11, 16, 19, and 44.

27. The method of Blum comprises using linear regression analysis of the mean values (column 104, lines 27-30 and column 105, lines 25-38) and standard deviation (Table 20-D), as in instant claims 23 and 24.

28. The method of Blum further comprises analysis using computerized database such as GenBank database available from the NCBI (column 37, lines 35-42), as in instant claim 25.

29. The ADRAC2C dinucleotide repeat polymorphism sequence is derived from the human genome database (column 176, lines 27-31). The linear regression analysis discussed above is performed using SAS software (column 111, lines 23-30), as in claims 26, 28-38, 41, 43, 48-50, 52-57, 59-61, and 71-77.

30. Blum suggests an improvement to overcome such impediments as false positives and un-reproducible data as directed genetic linkage of genes to polygenic disorders (column 21, 18-38). While, Luo et al. discloses a method for modeling genetic mapping of putative genes to polygenic traits (page 236, column 2, lines 5-19). Therefore, the improvement suggested by Blum is directly applicable to the method of Luo et al.

31. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement suggested by Blum to utilize a method of associating a phenotype with a candidate chromosome region(s) as directed to a phenotype wherein the said method comprises a clustering step and a genotype database. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use a method of associating a phenotype with a candidate chromosome region(s) as directed to a phenotype wherein the said method comprises a clustering step and a genotype database as taught by Luo et al. and Blum.

CONCLUSION

32. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

33. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to

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37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

34. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

35. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

36. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

37. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
3/11/04


ARDIN H. MARSCHEL
PRIMARY EXAMINER 3/16/04